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75	90 05/22/2002			
LISA A. HAILE, Ph.D. GRAY, CARY, WARE & FREIDENRICH LLP 4365 Executive Drive, Suite 1100			EXAMINER	
			SODERQUIST, ARLEN	
San Diego, CA 92121-2133			ART UNIT	PAPER NUMBER
			1743	18
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Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary

Application No. **09/409,644**

Applicant(s)

Lewis et al.

Examiner

Arlen Soderquist

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The MAILING DATE of this communication appears	on the cover sheet with the correspondence address			
Period for Reply				
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In				
mailing date of this communication. If the period for reply specified above is less than thirty (30) days, a reply within the set or extended period for reply within the set or extended period for reply will, by statute, cause the tarm of the set of th	and will expire SIX (6) MONTHS from the mailing date of this communication. The application to become ABANDONED (35 U.S.C. § 133).			
Status				
1) Responsive to communication(s) filed on <u>Feb 20, 2</u>	002			
2a) X This action is FINAL . 2b) This act	ion is non-final.			
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11; 453 O.G. 213.				
Disposition of Claims				
4) X Claim(s) 50-72, 85-90, and 98-158	is/are pending in the application.			
4a) Of the above, claim(s) <u>50-72 and 85-90</u>	is/are withdrawn from consideration.			
5) Claim(s)	is/are allowed.			
6) 💢 Claim(s) <u>98-158</u>	is/are rejected.			
7)	is/are objected to.			
8) Claims	are subject to restriction and/or election requirement.			
Application Papers				
9) \square The specification is objected to by the Examiner.				
10) The drawing(s) filed on Feb 20, 2002 is/are	a) \square accepted or b) $ ot\!\! $ objected to by the Examiner.			
Applicant may not request that any objection to the c	Irawing(s) be held in abeyance. See 37 CFR 1.85(a).			
11) The proposed drawing correction filed on	is: a) \square approved b) \square disapproved by the Examiner.			
If approved, corrected drawings are required in reply to this Office action.				
12) The oath or declaration is objected to by the Examiner.				
Priority under 35 U.S.C. §§ 119 and 120				
13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).				
a) ☐ All b) ☐ Some* c) ☐ None of:				
1. Certified copies of the priority documents have	re been received.			
2. Certified copies of the priority documents have been received in Application No				
3. Copies of the certified copies of the priority d application from the International Bure	au (PCT Rule 17.2(a)).			
*See the attached detailed Office action for a list of th				
14) Acknowledgement is made of a claim for domestic				
a) U The translation of the foreign language provisions				
15) ☐ Acknowledgement is made of a claim for domestic	priority under 35 U.S.C. 33 120 and/or 121.			
Attachment(s) 1) Notice of References Cited (PTO-892)	4) Interview Summary (PTO-413) Paper No(s).			
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) Notice of Informal Patent Application (PTO-152)			
3) Information Disclosure Statement(s) (PTO-1449) Paper No(s).	6) Other:			

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1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the associated detection equipment or the structure of the various types of sensors as found in claims 154-158 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

- 2. The proposed drawing correction and/or the proposed substitute sheets of drawings, filed on February 20, 2002 have been disapproved because they introduce new matter into the drawings. 37 CFR 1.121(a)(6) states that no amendment may introduce new matter into the disclosure of an application. The original disclosure does not support the showing of the specific compositions of the sensors to figure 1A. Examiner was unable to find a listing of the compositions of the sensor that make up the array of the figure and the listing as provided constitutes new matter.
- 3. Claims 98-147 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In each of the independent claims, the sensing area is composed of a material that is required to have a first response when contacted with a first analyte and a second different response when contacted with a second different analyte. It is not clear if this means that all materials which exhibit the same response for any two possible analytes are excluded as sensing materials or if the statement is actually non-limiting and unnecessary because no two responses can be identical. Or said another way, what constitutes a different response? For examination purposes the limitation will be treated as non-limiting. Additionally claims 98, 104-105, 107 and 126 contain the phrase "highly doped semi-conductor" which is a relative phrase that renders the claims indefinite. The phrase is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.
- 4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 98-99 and 104-105 are rejected under 35 U.S.C. 102(b) as being anticipated by Bruschi, Guiseppi-Elie, Matsumura or Thackeray (all newly cited and applied).

In the paper Bruschi discusses gas sensing with conducting polymer thin film resistors obtained from commercial photoresist patterns. Thin films of polypyrrole were obtained by polymerization from the vapor phase onto oxidizing patterns of commercial photoresist modified by addiction of chlorinated Cu nano-particles. The morphology and electrical characterization of the polypyrrole/photoresist films is described. The time stability and sensitivity to gases are presented.

In the patent Guiseppi-Elie presents chemical and biological sensors having electroactive polymer thin films attached to microfabricated devices and possessing immobilized indicator moieties. Chemical and biological sensors are provided that convert the chemical potential energy of an analyte into a proportionate electrical signal through the transducer action of a microfabricated device with an integral electroconductive polymer film. The microsensor devices possess a coplanar arrangement of at least one, and typically three, microfabricated interdigitated microsensor electrode arrays each with line and space dimensions that may range from 2-20 μ m and is typically 10 μ m, a platinized platinum counter electrode of area at least 10 times the area of the interdigitated microsensor electrode array and a chloridized silver/silver chloride reference electrode. Chemical and biological sensors constructed according to the present invention employ a thin electrical conducting polymer film that is specifically attached via covalent bond formation to the interdigitated microsensor electrode component of the devices. The electrically conducting polymer film is formed in many ways. Example 6 shows the polymer formed as a copolymer which examiner is holding as meeting the two different conductors limitation.

In the patent Matsumura presents doped acetylene polymers. Doped acetylene polymers useful as organic semiconductors for solar batteries, various sensors, etc. were produced by immersing an acetylene polymer under an inert gas atmosphere in an organic solvent solution of a

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dopant (a Pt group metal complex, a carbonium salt, an oxonium salt, or a p-benzoquinone derivative). A doped acetylene polymer having any desired electrical conductivity was produced.

In the paper Thackeray teaches chemically responsive microelectrochemical devices based on platinized poly(3-methylthiophene) and shows variation in conductivity with variation in hydrogen, oxygen, or pH in aqueous solution. Microelectrochemical transistors can be prepared by connecting 2 closely spaced (\sim 1.2 μ m) Au microelectrodes (0.1 μ m thick \times 2.4 μ m wide \times 50 μm long) with anodically grown poly(3-methylthiophene). The amount of poly(3methylthiophene) used involves about 10⁻⁷-10⁻⁶ mol of monomer/cm². Poly(3-methylthiophene) can be platinized by electrochemical reduction of PtCl₄²⁻ at the pair of coated electrodes. The change in conductivity of poly(3-methylthiophene) with change in redox potential is the basis for amplification of electrical or chemical signals; the conductivity varies by 5-6 orders of magnitude upon change in potential from +0.2 (insulating) to +0.7 (conducting) V vs. SCE in aqueous electrolyte. The Pt equilibrates poly(3-methylthiophene) with the O₂/H₂O or H₂O/H₂ redox couples. [Poly(3-methylthiophene)/Pt]-based transistors are shown to be viable roomtemperature sensors for O₂ and H₂ in aqueous solution. The O₂ reproducibly turns on the device, with 1 atmosphere of $O_2/0.1$ M HClO₄/H₂O showing 0.7-mA I_D at a V_D = 0.2 V; H₂ reproducibly turns off the device, with 1 atmosphere of H₂/0.1 M HClO₄/H₂O showing less than 20-nA I_D at a $V_D = 0.2 \text{ V}$, where V_D (drain potential) is the applied potential between the 2 Au microelectrodes and I_D (drain current) is the current that passes between the 2 microelectrodes. The turn on with O₂ is complete within 2 minutes, and the turn off with H₂ is complete within 0.3 minutes. A platinized microelectrode of a dimension similar to the microelectrochemical transistor shows only 1.0-nA reduction current upon exposure to 1 atmosphere of O2; the current amplification of the transistor is thus a factor greater than 10⁵. The transistor device can also reproducibly respond to pH changes in the pH range of 0-12, when there is a constant O₂ concentration; there is a reproducible change in I_D to alternate flow of a pH 5.5/pH 6.5 stream for over 10 h. The device responds to an injection of 10⁻⁶ L of 0.1 M HClO₄ into an effluent stream of 0.1 M NaClO₄ (flowing at 2 mL/min) within 4s. Study of the resistance properties of [poly(3methylthiophene)/Pt] vs potential reveals that Pt has little effect on the intrinsic conductivity of

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poly(3-methylthiophene). Rather, the role of Pt is purely as a a catalyst to allow equilibration of O_2 and H_2 with the polymer. The amount of Pt used in approximately 10^{-7} mol/cm², and microscopy shows Pt to be present as a particle of less than 0.1- μ m size.

- Claims 98-99, 104-109, 111-112, 119-120, 123-129, 134, 141-142 and 145-157 are 6. rejected under 35 U.S.C. 102(b) as a being anticipated by Gibson (newly cited and applied). In the patent application Gibson teaches an odor sensor. as a personnel recognition sensor comprises as a multiplicity of differentially responding chemo-resistor elements, each element comprising as a nonconductive substrate, as a plurality of electrodes disposed on the substrate and one or more layers of as a conductive polymer overlaying the electrodes, the conductive polymers of at least two of the elements being different; as a detector responsive to signals provided by the multiplicity of elements and arranged to provide an output signal characteristic of the multiplicity of signals; the elements being disposed in as a housing having an inlet arranged so that as a gaseous sample passing into or through the inlet contacts all of the elements in use. Page 12 teaches as a material having two different monomers used to form as a copolymer which examiner is treating as a within the scope of two different conducting materials. Page 13 shows several different polymeric materials that are usable in the invention. in the sentence after the list is given Gibson teaches that copolymers and blends of the polymers listed can be used as a the polymer. pages 14-15 teach the materials used as a sensing materials in the sensor of figure 1. Sensors 7, 10 and 15 use materials within the claimed scope.
- 7. The following is as a quotation of 35 U.S.C. 103(as a) which forms the basis for all obviousness rejections set forth in this Office action:

(as a) as a patent may not be obtained though the invention is not identically disclosed or described as a set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a as a whole would have been obvious at the time the invention was made to as a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing as a background for determining obviousness under 35 U.S.C. 103(as a) are summarized as a follows:

1. Determining the scope and contents of the prior art.

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- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
- 8. Claims 98-158 are rejected under 35 U.S.C. 103(as a) as a being unpatentable over Gibson as a applied to claims 98-99, 104-109, 111-112, 119-120, 123-129, 134, 141-142 and 145-157 above, and further in view of Casella (newly cited and applied), de Lacy Costello, Rajeshwar, Yamato (newly cited and applied), Bruschi, Guiseppi-Elie, Matsumura or Thackeray (last four as a discussed above) and Breheret (newly cited and applied), Mifsud (both US 5,801,297 and WO 95/08113, newly cited and applied), Moy (newly cited and applied) or Persaud (WO 86/01599, newly cited and applied). Gibson does not teach the extent of the compositions in which the two conductive materials are mixed together to form as a single sensing material having the compositionally different conductive material within the conductive organic material or as a sensing array having sensors that are not organic polymer based.

In the paper Casella discusses Copper dispersed into polyaniline films as a an amperometric sensor in alkaline solutions of amino acids and polyhydric compounds. as a chemically modified electrode composed of copper microparticles dispersed into as a polyaniline (PANI) film was studied as a an amperometric sensor of scantly electroactive compounds possessing -OH and -NH₂ groups. Glassy carbon was used as an electrode material and modified firstly by a PANI film, then allowed to stand in contact with a solution of copper ions, and finally, the electroreduction was done at -0.3V. The electrochemical behavior of the resulting modified electrode in alkaline medium was examined by cyclic voltammetry and flow-injection amperometry. Using some representative compounds, the effect of copper loading and pH on the electrode response was studied. Constant-potential amperometric detection was applied in conjunction with anion-exchange chromatography (AEC) separations of amino acids and carbohydrates. At an applied potential of 0.55 V vs. Ag/AgCl, the detection limits (S/N = 3) for all analytes studied ranged 5-15pmol, and the linear dynamic range was three-four orders of magnitude above the detection limits. The resulting modified electrode was found to retain 95% of its initial response in flowing streams for 3 hours of operating time.

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In the paper de Lacy Costello teaches composite organic-inorganic semiconductor sensors for the quantitative detection of target organic vapors. Composites of tin dioxide (an n-type semiconductor) and derivative of the conducting polymer polypyrrole (a p-type semiconductor) gave reversible changes in electrical resistance at room temperature when exposed to a range of organic vapors. The optimum amount of polymer giving highest sensitivity was found to be 2.5% by mass for the polypyrrole chloride-tin dioxide composite. Composites containing 2.5% polymer by mass, but differing in polymer derivative were fabricated and exposed to low concentrations of ethanol, methanol, acetone, methyl acetate and ethyl acetate. All gave significant and reversible decreases in electrical resistance. Direct comparison with sensors constructed solely of tin dioxide or polypyrrole at room temperature showed the composites to be more sensitive. The gas sensitivity of the composite materials depended on the type of polymer derivative incorporated and the dopant anion associated with the polymer. The composites were simple to fabricate and gave differing response profiles to a range of organic vapors.

In the paper Rajeshwar presents polypyrrole composites containing platinum or carbon black and discusses the synthesis and applications of the material. Modification of the electrochemical properties of polypyrrole with platinum or carbon black is described. These composites exhibited enhanced properties relative to the neat polymer. The use of these materials in new applications involving pollutant remediation/sensing, and in supercapacitor devices was demonstrated.

In the paper Yamato presents a new method for dispersing palladium microparticles in conducting polymer films and its application to biosensors. Composite films of polypyrrole/sulfated poly(β-hydroxyethers) (PPy/S-PHE) are electrically conducting and mechanically flexible. Palladium particles were dispersed in the films by thermally decomposing bis(dibenzylideneacetone)palladium(0) complex which had been absorbed by the films from a CHCl3 solution. This method for loading metal particles was enabled by the high affinity of the composite films for organic compounds. TEM and energy-dispersive x-ray spectrometry (EDX) analyses revealed that fine palladium particles in the nanometer range are dispersed in the PPy/S-PHE conducting films. A glucose sensor based on the detection of hydrogen peroxide was

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prepared by immobilizing glucose oxidase (GOD) using glutaraldehyde on a Pd/PPy/S-PHE electrode. This biosensor responded to glucose even at 400 mV vs. Ag/AgCl, which is lower than the working potential of conventional glucose sensors prepared on a platinum electrode.

In the paper Breheret presents online differentiation of mushrooms aromas by combined headspace/multi-odor gas sensors devices. A specially designed measurement cell for direct headspace analysis, online connected to (i) a gas chromatograph equipped with an headspace injector and a sniffing-port, (ii) multisensors devices: five semiconductor gas sensors and twenty conducting polymer gas sensors, was used to discriminate nine mushrooms' aromas. The raw data of gas sensors were statistically processed, and provided pictorial presentation under sample distribution in a plan, allowing to compare the different mushrooms' aromas, with the GC/sniffing analysis. Semiconductor gas sensors succeeded in classifying four groups based on overall odor. Semiconductor gas sensors seem to be more appropriate for the mushrooms aromas discrimination than conducting polymer gas sensors. These preliminary results confirm the interest of such technologies for chemotaxonomy differentiation of wild mushrooms.

In the patent and patent application Mifsud tteaches methods and devices for the detection of odorous substances and applications. A device for carrying out a method of odor detection including, in particular, a plurality of chambers, each having a plurality of semi-conductor gas sensors, conductive polymer gas sensors, surface acoustic wave gas sensors, as detection means, a variable flow gas pump for forming a gas flow in said chambers, measurement electronic device for operating the detection means, a data processing unit for recording in a file the olfactory prints obtained using the detection means, and for comparing the detected impressions with those in the file so that odors may be identified and recognized. Applications, especially to drugs, explosives, body odors and food seals.

In the paper Moy discusses transient signal modeling for fast odor classification. The Fox 2000 is an electronic nose system using an array of 6, 12, or 18 gas sensors. The anal. of sensor signals coming from a combination of metal oxide sensors and conducting polymer elements indicates the ability of predicting in only a few seconds the nature of a sample (hams, sausages, cereals...) from its olfactory fingerprint. The simulation of the signals is performed via

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exponential functions and applied to various foodstuffs. Online and real time Artificial Neural Network (ANN) have also been investigated for fast odor classification and recognition. Six different brands of sausages (pure pork, beef/pork sausages) have been analyzed using a 6-element array. Six samples of each type of sausage were measured 12 times and discriminant analysis was performed over the set of 72 samples using the raw data of acquisition. 94% Of the samples were correctly classified and cross validation (testing unknown samples) gave an overall success rate of 83% correctly classified samples. These results indicate the possibility to use electronic noses and pattern recognition methods for fast odor classifications.

In the published application Persaud treaches gas sensors. A sensor for gases, vapors, or odors has an organic polymeric semiconductor element which changes its electrical resistance in the presence of certain gases. The polymer is formed by electrolytic deposition on the substrate from a solution of its monomer, the solution comprising a solvent medium in which the monomer is sparingly soluble, a protic solvent, and an ionic base. A number of different gas detectors can be used to obtain from each a characteristic response to the presence of a gas, and the combination of responses can be used to distinguish between gases. The different detectors may be all based upon organic polymers, or one or more detectors may use other principles such as flame ionization or gas chromatography. The sensor is useful in monitoring industrial environments, gas liquid chromatography, quality control in food and drinks production, and food production. Page 14, line 2-9 teach that the different types of sensors can allow the device to detect between odors that it might not otherwise be able to discriminate. Page 16, lines 15-21 teach that an alternative form of the sensor is as a polymer coated field effect transistor.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the teachings of Bruschi, Casella, de Lacy Costello, Guiseppi-Elie, Matsumura, Rajeshwar, Thackeray or Yamato relative to the incorporation of conductors such as carbon black, metal particles and tin dioxide into the conductive organic polymers used in the sensing arrays of Lewis because of the enhanced properties as taught by each of Bruschi, Casella, de Lacy Costello, Guiseppi-Elie, Matsumura, Rajeshwar, Thackeray or Yamato. It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate

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other types of sensors such as the metal oxide and/or surface acoustic wave devices taught by Breheret, Mifsud, Moy or Persaud into the Gibson device because of the ability to use them in combination to discriminate odors that would not easily be discriminated by a single type of sensor as taught by Breheret, Mifsud, Moy or Persaud.

- 9. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection. A comment relative the temperature coefficient of the inorganic conductor would be appropriate. Examiner notes that some of the independent claims do not require any type of temperature coefficient (108, 128, 148 and 152). Thus, any argument to this aspect of certain claims is not commensurate in scope with these claims or those claims that depend therefrom.
- 10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The additionally cited art relates to materials or structures uased in detection sensors.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arlen Soderquist whose telephone number is (703) 308-3989. The examiner's schedule is variable between the hours of about 5:30 AM to about 5:00 PM on Monday through Thursday and alternate Fridays.

For communication by fax to the organization where this application or proceeding is assigned, (703) 305-7719 may be used for official, unofficial or draft papers. When using this number a call to alert the examiner would be appreciated. Numbers for faxing official papers are

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703-872-9310 (before finals), 703-872-9311 (after-final), 703-305-7718, 703-305-5408 and 703-305-5433. The above fax numbers will generally allow the papers to be forwarded to the examiner in a timely manner.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Arlen Society ust May 17, 2002

ARLEN SODEHUUIST PRIMARY EXAMINER